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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HOWARD, SHARON LEE

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 05/05/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/044,113

Applicant(s)

REAM ET AL.

Examiner

Sharon L. Howard

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 8-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Applicant's election without traverse of Group II, claims 8-20 in Paper No. 6 is acknowledged.

Claims 8-20 are pending in this application.

***Claim Rejections - 35 USC § 112***

Claims 8,9,16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 16 the word "including" which is indefinite. Is the medicament part of the product? It is suggested that applicant remove the word "including" and insert the word "comprising".

Claims 9 and 17 contain the words "chosen from the group consisting of analgesics, muscle relaxants, ..... bioengineered pharmaceuticals, and cardiovascular agents" which is improper Markush language. Proper Markush language is "selected from the group consisting of analgesics, muscle relaxants, ... bioengineered pharmaceuticals, and cardiovascular agents". Also, the words "vitamins, minerals" have been recited twice in claims 9 and 17. Clarification is requested.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri (U.S. Patent No. 4,317,838) in view of Niazi et al. (U.S. Patent No. 4,639,368).

Cherukuri teaches a chewing gum product comprising confections and a sugarless coating. Cherukuri teaches a method for applying to the gum center, a sugarless coating consisting of sweeteners such as sorbitol, mannitol (col.2, lines 60-64), from about 0.04 to about 2% of synthetic sweeteners which include cyclamate salts or free saccharin acid (col.3, lines 18-21). Cherukuri teaches that it is known in the art to apply two or more coats of each of the coating syrup and dusting mix in order to build up a desired thickness and coating weight on the gum centers (col.2, lines 14-30). Cherukuri teaches that the comestible to be coated may include edible pressed candies and hard candies and other confections, and medicinals in the form of tablets (col.5, lines 55-60).

Cherukuri does not teach a particular medicament.

However, Niazi teaches a chewing gum composition comprising a gum base and a medicament (col.2, lines 20-23). Niazi teaches that the chewing gum is the carrier for the medicament (col.2, line 28) and that depending upon the particular drug used and the type of gum product desired, the amount of the medicament will vary (col.2, lines 36-41, generally in the amount of from about 0.5 milligrams of medicament per stick of chewing gum composition to about 500 milligrams of drug per stick of chewing gum composition (col.4, lines 53-61)). Examples of the medicament known to be used in the composition include analgesics, laxatives, antacids, vitamin B12 and trace mineral

Art Unit: 1615

supplements and local antibiotics (col.4, lines 14-52). Niazi also teaches sweeteners such as aspartame or other sugar alcohols (col.2, lines 56-68, col.3, lines 1-11) and a taste masking agent (col.4, lines 62-68, bridging col.5, lines 1-15).

Both references teach chewing gum compositions comprising sweeteners. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. **See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).**

The expected result would be a composition comprising confections, and a sugarless coating which comprises a medicament that surrounds the center of a chewing gum.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teaching of Cherukuri and the Niazi reference. One having ordinary skill in the art would have been motivated to modify the composition of Cherukuri to include a medicament, because the third composition can be used for the same purpose of coating the center of a chewing gum.

Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri ('838) in view of Cherukuri et al. (U.S. Patent No. 4,753,805).

The primary reference is applied above.

The primary reference does not particularly teach a medicament.

However, the secondary reference ('805) teaches a tabletted chewing gum composition comprising a gum base, saccharides which include dextrose, and sucrose, sweetening agents such as corn syrup solids and sugar alcohols such as sorbitol and mannitol, about 0.05% to about 2.5% of artificial sweeteners such as saccharin salts and acesulfam-K and the like (col.6, lines 8-68 and col.7, lines 12-16), and medicaments (col.8, lines 62-68, bridging col.9, lines 1-50). The reference teaches medicaments such as vitamins, minerals, antacids and caffeine which can be incorporated in the gum tablets (col.9, lines 30-50).

Both references teach chewing gum compositions. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. **See In re Kerkhoven 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).**


The expected result would be a chewing gum composition comprising a sugarless coating which comprises a medicament that surrounds a tabletted center.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of the primary reference and the secondary reference. One having ordinary skill in the art would have been motivated to modify the composition of the primary reference to include a medicament, because the third composition can be used for the same purpose of coating the center of a chewing gum.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (703) 308-4359. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3121 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



Sharon Howard  
April 4, 2003



CARLOS A. AZPURU  
PRIMARY EXAMINER  
GROUP 1500